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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,064	01/10/2006	Salvatore Daidone	284222US0PCT	3939
22850 7590 07/13/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.		EXAMINER		
1940 DUKE STREET			TOUSSAINT, DALILA	
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			1794	
			NOTIFICATION DATE	DELIVERY MODE
			07/13/2009	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com oblonpat@oblon.com jgardner@oblon.com

	Application No.	Applicant(s)				
Office Action Comments	10/564,064	DAIDONE, SALVATORE				
Office Action Summary	Examiner	Art Unit				
	DALILA TOUSSAINT	1794				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on						
	-· action is non-final.					
<i>,</i> —	,—					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
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Disposition of Claims						
4) Claim(s) <u>1-19</u> is/are pending in the application.						
4a) Of the above claim(s) <u>5-8</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some color None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) \[ \sum \text{Notice of References Cited (PTO-892)} \]	4) ☐ Interview Summarv	(PTO-413)				
2) Notice of Praftsperson's Patent Drawing Review (PTO-948)	4)					
3) Information Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal P	atent Application				
Paper No(s)/Mail Date 6) L. Other:						

Art Unit: 1794

#### **DETAILED ACTION**

This action is responsive to the reply filed on April 14, 2009. Claims 1-4 and 9-19 are pending and claims 5-8 stands withdrawn as non-elected invention.

#### Election/Restrictions

1. Newly submitted claim 8 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 8 is dependent upon an independent claim withdrawn form further consideration pursuant to being drawn to a nonelected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 8 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### Claim Rejections - 35 USC § 112

2. The 112 second paragraph rejection is hereby withdrawn in view of applicant's amendment.

### Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1794

4. Claims 1, 3-4, 9-14, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Narayan et al. WIPO publication 02/13631 A1.

- a. Referring to claims 1 and 17-19, Narayan et al. teaches:
  - (1) A water-soluble salt tablet (page 8, line 18) comprising:
    between 20 to 99.9% by weight of NaCl, iodine, K ions, Ca
    ions, and Mg ions being present as the chlorides and/or
    sulphates thereof (page 2, line 9-18 and page 4, line 18-24),
    wherein said tablets are formed from dehydrated granules
    having a particles size range from 500 microns to 5,000
    microns (page 7, line 28) and wherein the Mg ions are
    present in an amount between 0 to 10% by weight of soluble
    chloride or sulphate salt of magnesium (page 6, line 9-10).

Based on Narayan et al. disclosure the Mg ions would be present about 0% and 2.5% by weight on a dry basis, as calculated based on the weight of the salts.

- b. Referring to claim 3, Narayan et al. teaches a predetermined weight as shown by the disclosure on page 4, lines 18-27.
- c. Referring to claim 4, Narayan et al. teaches:
  - (2) The water-soluble salt tablet as claimed in claim 2, wherein said salt is a natural integral sea salt (page 1, line 10 and 13).
- d. Referring to claims 9-10, Narayan discloses an edible salt comprising 20 to 99.9% by weight sodium chloride (page 6, line 7).

Art Unit: 1794

e. Referring to claims 11-14, Narayan discloses an edible salt wherein K ions are present between 0.1 to 80% by weight potassium chloride and Ca ions are present between 0 to 10% by weight of water soluble chloride or sulphate salt of calcium (page 3, line 21-23).

#### Claim Rejections - 35 USC § 103

- 5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 6. Claims 2 and 15-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Narayan et al. WIPO publication 02/13631 A1 and further in view of R. Aquaron, ["lodine content of non iodized salts and iodized salts obtained from the retail markets worldwide ", 8th World salt symposium, vol. 2, pages 935-940].
  - f. Referring to claims 2 and 15-16, Narayan et al. teaches:
    - (3) The water-soluble salt tablet according to claim 1, comprising:

Wherein, K ions are present between 0.1 to 80% by weight potassium chloride and Ca ions are present between 0 to 10% by weight of water soluble chloride or sulphate salt of calcium (page 3, line 21-23).

Narayan et al. also disclose the use of iodine in its embodiment (page 3, line 9-11) and that it meets the statutory requirement level of iodine in salt.

Art Unit: 1794

However, Narayan et al. fails to explicitly disclose the composition of iodine between 0.00053% and 0.0012% in its embodiment.

The reference by R. Aquaron discloses that the iodine content in salt water varies with various locations. Since the claim does not include any particular location and based on the knowledge that sea salt contains trace amounts of iodine as shown in the disclosure of R. Aquaron, the mandatory iodine level in salt would be expected to be met by Narayan et al. (Narayan et al.; page 3, line 10). Furthermore R. Aquaron discloses iodine is a very important trace element, necessary for the biosynthesis of thyroid hormones (Aquaron; page 1, column 1, ¶ 1), wherein current iodization levels according to specific country legislation vary from 20 to 100 ppm of KI or KIO3 (Aquaron; page 6, column 1, ¶ 2). It would have been obvious that iodine would be present in the amount claimed, as a result effective variable based on geographical location. Again, Narayan et al discloses the iodine in salt would be expected to meet the requirement. It would not be unreasonable, absent a showing to the contrary, that the combined references disclose the amount of the instant claims.

## Response to Arguments

7. Applicant's arguments filed April 14, 2009 have been fully considered but they are not persuasive.

Applicant argues Narayan does not describe or suggest forming a salt tablet from dehydrated granules having a particle size distribution between 0.8 mm to 1.1 mm.

In response to argument, Narayan discloses various options to forming tablets such as spherical particles, irregular shape spheres, noodles and others through methods known in the art of forming granules (Narayan; page 7, line 24-page 8, line 20). Narayan, further disclose drying the granules made by an additional drying step (page 8, line 20-25). The granules such as noodles or other irregular shaped granules, in the size range of 500 microns to 5,000  $\mu$ , can be dried and then subjected to a process with sufficient force and pressure and attrition to cause the granules to round off to spheres (page 8, line 8-11). Narayan, further disclose forming the tablets or granulated salts with a blend of salts with a particles size of more than 500 microns or with crystal salt with a size of about 2 mm (page 9, line 7-10). It is held that where the claimed and prior art are identical or substantially identical in structure, a prima facie case will be considered to have been established over the claimed structure.

Applicant argues Narayan forms a non-tableted free-flowing spherical particle of wet salt, which does not describe or suggest salt tablets formed from dehydrated granules.

Again as disclosed above, Narayan discloses various options to forming tablets, one option is by spraying or applying a wet solution and then granulating, as applicant discloses, forming tablets or granules with a blend of salts having a particles size of more than 500 microns or with crystal salt with a size of about 2 mm (page 9, line 7-10). The granules may be dried by an additional drying step (page 8, line 20-25). Another option is to take dried granules such as noodles or other irregular shaped granules, in the size range of 500 microns to 5,000  $\mu$ , and subjecting them to a process with

sufficient force and pressure and attrition to cause the granules to round off to spheres (page 8, line 8-11). Concluding the granules may be taken from a high moisture content to a lower moisture content, consequently dehydrated granules.

Also, the claims recite a tablet; which in a reasonable broad interpretation would include pellets, spheres, solidified substances, granules, etc.

Applicant argues Aquaron does not remedy the deficiencies of Narayan.

In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, the reference by R. Aquaron discloses that the iodine content in salt water varies with various locations. Since the claim does not include any particular location, based on the knowledge that sea salt contains trace amounts of iodine as shown in the disclosure of R. Aguaron, the mandatory iodine level in salt would be expected to be met by Narayan et al. (Narayan et al.; page 3, line 10). Furthermore R. Aquaron discloses notable amounts of iodine is a very important trace element, necessary for the biosynthesis of thyroid hormones (Aquaron; page 1, column 1, ¶ 1), wherein current iodization levels according to specific country legislation vary from 20 to 100 ppm of KI or KIO3 (Aguaron; page 6, column 1, ¶ 2). It would have been obvious that iodine would be present in the amount claimed, as a result effective variable based on geographical location. Again, Narayan et al discloses

Art Unit: 1794

the iodine in salt would be expected to meet the requirement. It would not be unreasonable, absent a showing to the contrary, that the combined references disclose the amount of the instant claims.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DALILA TOUSSAINT whose telephone number is (571)270-7088. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST.

Art Unit: 1794

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571)272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DT

/KEITH D. HENDRICKS/ Supervisory Patent Examiner, Art Unit 1794